Casey D. Hathcock, Ph.D.

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Summary

I am a motivated medical device product development engineer with a creative, versatile, and detail-oriented skill set. My experience includes treatment of acid reflux disease, automated CPR delivery, home hemodialysis, robotic catheters, venous reflux disease, through all stages of design control. With knowledge in medical device standards such as ISO13485 ISO60601 and FDA 510k submission process, I enjoy working with cross-functional team members to ensure on time delivery of high-quality, safe, and effective products to market.

Employment

EndoGastric Solutions, Redmond, WA (acquired by Merit Medical)

Feb 2016 – Dec 2024, Principal R&D Engineer

- Delivered the EsophyX Z+ Device within a 9-month timeline. Product has generated approx. 30% YOY sales growth. My contribution to this project included:
  - Interface with physicians to determine user requirements and translate to product specifications.
  - Designed new injection molded, including overmolded components, and machined components.
  - Interfaced with vendors, coordinated first article inspections, and component changes needed.
  - Qualified new components and conducted device design verification.
  - Wrote design validation protocol, interfaced with sales and physicians to execute protocol, and wrote report.
- Current role is focused on Technical Leadership and Project Management of new product in development and sustaining engineering.
- Leader for technical 510k submission.
- Designed and fabricated verification tooling and test fixtures.
- Performed root-cause analysis on device returns and drove changes to mitigate design problems.
- Drove design changes to reduce system cost of materials by approx. 5%.

ZOLL Medical, San Jose, CA

Mar 2015 – Feb 2016, Principal Mechanical Engineer

- Designed next-generation automated CPR platform, lithium-ion battery pack, and battery charger system.
- Determined user needs and product requirements by interfacing with emergency medical response teams and fire crews.
- Produced physical prototypes that were used in customer feedback using Solidworks, 3-axis CNC mill, manual mill, manual lathe, FDM, and SLA.
- Improved existing product design and manufacturing methods.

Outset Medical, San Jose, CA

June 2014 – Mar 2015, Principal Development Engineer

- Responsible for development of mechanical assemblies and enclosure for next generation home hemodialysis system.
- Enhanced user interaction of mechanical interface using SolidWorks, FEA, tolerance analysis, and prototype construction.
- Performed root cause analysis of aluminum extrusion chassis and thermoformed enclosure components leading to significant improvements to chassis design and enclosure form and fit.
- Improved manufacturability and serviceability of the system.

Johnson & Johnson, Mountain View, CA (formerly Hansen Medical)

Jan 2014 – June 2014, Staff Mechanical Engineer

- Designed and implemented new skins on Robotic Catheter System. New skins were debuted at Heart Rhythm Society Meeting in May 2014.
- Used Design of Experiments and other statistical techniques to efficiently obtain objective data on complex robotic wire manipulator systems to define system requirements.
- Lead RoHS assessment of mechanical components on Robotic Systems. RoHS compliance documentation completed June 2014.

Medtronic, San Jose, CA (formerly VNUS Medical)

Aug 2007 – Dec 2013, Principal R&D Engineer

- Responsible for electromechanical design and development of 3rd generation ClosureRFA™ product from concept through design verification
  - Defined system industrial design based on customer preference testing.
  - Developed early-stage prototype RF Generators using in-house CNC machining and welding equipment.
  - Designed Class A surface enclosure, EMI/RFI shielding, and electronics packaging.
  - Teamed with mold tooling and sheet metal vendors to meet project and mechanical design requirements.
- Lead software V&V on CLF-3 Catheter Project. Product launched on schedule in August 2011.
- Performed gap analysis of IEC 60601 standards to determine compliance of RF generator. Awarded CE mark by TUV SUD in February 2011.
- Established test methods, acceptance criteria, and test equipment for all stages of product development.

Avocet Polymer Technologies, Plainfield, IL

Jan 2005 – June 2007, Senior Research Engineer

- Project Lead Engineer - electronic non-lethal weapon device contract research ($1.2M revenue).
- Project Lead Engineer – processed scalpel blade assessment contract research ($325k revenue).
- Lead diverse groups including engineers, surgeons, physiologists, post-doctoral fellows, and research associates.

Education

2006 **Ph.D. Bioengineering** University of Illinois at Chicago, Chicago, IL

1999 **B.S. Biology** University of Missouri, Columbia, MO

Experience and Skills

Analytical Techniques

- Trained in Design for Six Sigma

Tolerance analysis	Hypothesis testing	MSA/Gage R&R
Regression analysis	Design of Experiments	Finite Element Analysis

Computer and Software Skills

- Certified SolidWorks Professional, License: **C-H7WBRPMVS6**, Awarded June, 2013

SolidWorks, EPDM	CAMWorks, HSM Works	Microsoft Office Suite
Arena, Agile PLM	Minitab, JMP	Adobe Illustrator
Python, R, MATLAB, C, C++	Github, ClearQuest, JIRA	Requisite Pro, Doors

Materials and Fabrication Experience

I am familiar with manual and automated technologies used to machine, mold, bend, cast, and form parts. I am experienced in specifying materials and material coatings to protect against corrosion and

degradation of part-part interfaces. I am well versed in the machine shop, which has led to quick turn prototypes and constructive feedback in terms of feasibility and design for manufacturing.

- Designed and fabricated RF Generator prototype sheet metal enclosures using CNC machining and TIG welding.
- Used Tormach and Fadal CNC 3-axis mill, Bridgeport manual mill, and manual lathe to build prototype medical devices.
- Used additive processes such as fused deposition modeling, stereolithography, and multijet printing.
- Fabricated devices using MEMS techniques such as photolithography, metal deposition, chemical vapor deposition, and reactive ion etching.
- Woodworking is a hobby and I have designed and built many furniture pieces, cabinetry, tables, and counter tops.

Animal Research Experience

I have over ten cumulative years of small and large animal research experience.

Volunteer Experience

- 2023-present, Woodinville Little League, Board Member
- 2022-present, First & Goal Hospitality, non-profit organization fund-raising staff.
- 2017-present, Woodinville Little League, manager and head coach of two softball teams.
- June 2012, Habitat for Humanity.